

DETAILED ACTION

Applicants' amendments, remarks and response dated 3/17/2011 is acknowledged. Applicants' have amended claims 1, 4, 18 and 27. Applicants have cancelled claims 2, 3, 5-7, 9, 15-17, 20-21. Claims 1, 4, 8, 10-14, 18, 19, 22-27 are free of prior art and are found to be allowable. The claims are renumbered as 1-16.

Application Priority

This application filed 4/28/2006 is a national stage entry of PCT/SE04/01001, International Filing Date: 06/23/2004, claims foreign priority to 0301862-9, filed 06/26/2003.

Information Disclosure Statement

The information disclosure statement (IDS) filed on 12/7/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS is being considered by the Examiner.

REASONS FOR ALLOWANCE

Applicants' amendments and arguments necessitated the withdrawal of the 112(1) and 103 rejections. Applicants' amended claims are limited to composition that is essentially free of a bacteriostatic agent other than pentane-1,5 diol. The rejection of claims 1, 18 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577 is withdrawn due to this application is the earlier filed application and 11/791,577 is the later filed application and also this is the

only pending rejection because Applicants' amendments and arguments necessitated the withdrawal of the 112(1) and 103 rejections.

The following is an examiner's statement of reasons for allowance:

The claims of the instant application are drawn to a method of inhibiting the growth of multiple resistant bacteria comprising topical administration of a pharmaceutical composition comprising 15% by weight or more of pentane-1,5-diol as multiple resistant bacteria, wherein said composition is essentially free of a bacteriostatic agent other than pentane-1,5-diol and multiple-resistant bacteria is at least one member of the group consisting of *Staphylococcus aureus* resistant to methicillin or fucidic acid, coagulation- negative staphylococci resistant to fucidic acid, *Enterococcus* resistant to fucidic acid, vancomycin, ciprofloxacin or trimetoprim, *Acinetobacter* resistant to cefadroxil, nitrofurantin or mecillinam, *Pseudomonas aeruginosa* resistant to vancomycin, ciprofloxacin or trimetoprim, and trimetoprim resistant *E. coli*.

The closest prior art are Swanbeck et al. (U.S. 5,369,129), Goodman et al. (U.S. 6,348,203), Medical Technology, 1991, Vol.19, No.11, p.978-98. Swanbeck et al. teaches a preparation for topical treatment of infections caused by virus, fungi, bacteria comprising 1, 5 pentane diol. The reference teaches a composition comprising 50% of 1, 5 pentane diol and 50% ethanol solution (see abstract, col1, lines 56-57). Swanbeck do not teach a composition comprising 1, 5 pentane diol wherein composition is essentially free of a bacteriostatic agent other than pentane-1,5-diol or do not teach administration of such composition in the treatment of multiple-resistant bacteria as

claimed. Goodman et al. teaches composition comprising antimicrobially active nitroimidazole drug (0.75% in example 1), the water-miscible organic solvent is a water-miscible alkylene glycol that includes pentylene glycol (synonym of 1,5 pentylene glycol or 1, 5 pentane diol) in treating infections. The reference do not teach a composition that is essentially free of a bacteriostatic agent other than pentane-1,5-diol in inhibiting the growth of multiple-resistant bacteria. The document Medical Technology, 1991, Vol.19, No.II, p.978-98 teaches ethanol in treating MRSA. However the document does not teach pentane 1,5 diol in treating Staphylococcus aureus resistant to methicillin or fucidic acid, coagulation- negative staphylococci resistant to fucidic acid, Enterococcus resistant to fucidic acid, vancomycin, ciprofloxacin or trimetoprim, Acinetobacter resistant to cefadroxil, nitrofurantin or mecillinam, Pseudomonas aeruginosa resistant to vancomycin, ciprofloxacin or trimetoprim, and trimetoprin resistant E. coli. It would have not been obvious to a person of ordinary skill in the art at the time of the invention to have specifically picked 1,5 pentane diol amongst numerous alcohols or diols available. Swanbeck or Goodman teaches compositions comprising 1,5 pentane diol with another bacteriostatic agent such as ethanol or nitroimidazole drug in treating infections. The closest prior art do not teach the claimed method of inhibiting the growth of multiple resistant bacteria comprising topical administration of a pharmaceutical composition comprising 15% by weight or more of pentane-1,5-diol as multiple resistant bacteria, wherein said composition is essentially free of a bacteriostatic agent other than pentane-1,5-diol and multiple-resistant bacteria, as in claim 1, 18 or 27. The claimed

invention is not obvious in view of the cited references. Hence the claims are allowable for the reasons stated above.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627